REMARKS

Summary

Claims 1-4, 6-8, 24-28, and 31-35 are pending. Claims 20-23 are cancelled, claims 27-28 are amended, and claims 32-35 are newly added. No new matter is added.

Allowable Subject Matter

Applicants thank the Examiner for the indication that claims 20-23 and 31 contain allowable subject matter. Accordingly, claims 20-23 have been rewritten in independent form as new claims 32-35. Thus, claims 31-35 are allowable.

Objections to Claims 27-28

Claims 27-28 are objected to for being dependent on a cancelled claim. The dependency of claims 27-28 has been changed to address the objection.

102(b) Rejection of Claims 1-4, 6, and 24-26

Claims 1-4, 6, and 24-26 are rejected under 35 USC 102(b) as being unpatentable over US Patent No. 4,919,141 to Zier et al. (Zier). Applicants respectfully traverse the rejection in light of the remarks below.

Zier provides an implantable electrochemical sensor having a sensing electrode 14 surrounded by insulating resin 12, which is further surrounded by a cannula 10. The arrangement defines a device, the tip of which may be covered by an enzyme layer 20 and a membrane 18 (such as porous polyurethane). However, enzyme layer 20 and membrane 18 merely cover the tip of the device, and do not surround sensing electrode 14 and do not surround insulating resin 12, as shown clearly by Figures 1-3. In addition, Column 5, lines 4-9, specifically describes this arrangement by stating:

> The measurement electrode 14, 14' can be embedded in a synthetic resin filler 12 in an axial direction with an end directed toward the pinpoint 16 of the cannula and with a free end covered with the enzyme layer 20. The tip of the cannula can be covered with a membrane 18 . . . .

The language used in Zier distinguishes the relationship between electrode 14 and resin 12 (embedded in an axial direction) from (1) the relationship between the end of electrode 14 and enzyme layer 20 (free end covered), and (2) the tip of the cannula and membrane 18 (tip can be covered). Thus, Zier teaches that resin 12 may surround electrode 14, while enzyme layer 20 merely covers the free end of electrode 14 and membrane 18 merely covers the tip of the cannula. Therefore, as shown in Figures 1-3 and the supporting text, Zier provides a membrane and/or enzyme layer that merely covers the active surface, but does not surround the active surface. In addition, as shown in Figures 1-3 and the supporting text, Zier provides a membrane and/or enzyme layer that merely covers the resin, but does not surround the resin.

However, claim 1 provides a membrane system comprising an enzyme layer, the enzyme layer surrounding the sensing region of the electrochemically active surface to form an active sensing region and surrounding the at least one nub. As has been discussed at length, the term "surround" provides for one element to encircle one or more other underlying elements. This understanding was stated clearly at page 2, lines 6-10, of the September 13, 2007 Office Action. This understanding is also consistent with the prior discussions on the subject, and is consistent with the representation in Figure 2 of the present application. In a general sense, the term "surround" is intended to mean that the membrane provides a covering/coating encircling the stated underlying element(s). When considering the scope of the term, reference to Figure 2 shows that the membrane system does not simply cover or abut an end of the device, but rather encircles the active surface and the nub(s).

Thus, Zier fails to teach at least one feature of claim 1, and therefore, claim 1 is patentable over Zier.

Claims 2-4, 6, and 24-26 depend directly or indirectly on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Zier, so are claims 2-4, 6, and 24-26 by virtue of at least their dependency.

103(a) Rejection of Claims 1-4, 6-8, 24, and 25

Claims 1-4, 6-8, 24, and 25 are rejected under 35 USC 103(a) as being unpatentable over US Patent No. 3,900,382 to Brown (Brown) in view of US Patent No. 5,063,081 to Cozzette et al. (Cozzette). Applicants respectfully traverse the rejection in light of the remarks below.

Brown is cited for teaching an electrochemically active surface 13, a dielectric layer 14, and membranes 18 and 19. More specifically, Brown provides an electrode lead 11 with a base member 12 and an electrochemically active surface 13. Surface 13 differs from surface 12 in that active surface 13 is an oxidized form of the metal surface of base member 12. As such, surface 13 provides an electrochemically active region, while base member 12 does not. Base member 12 is surrounded by insulation 14 to separate it from reference electrode 15. Electrochemically active surface 13, however, is not surrounded at any point by insulation 14 (see Figure 1).

Claim 1 of the present application is distinguishable in providing at least one nub of dielectric material extending outwardly from the electrochemically active surface. Brown does not provide such an arrangement.

In addition, electrochemically active surface 13 is surrounded by electrolyte 17. Electrolyte 17 is in-turn surrounded by membrane 18.

Claim 1 of the present application is distinguishable in providing a membrane system surrounding the sensing region of the electrochemically active surface. Brown does not provide such an arrangement.

Claim 1 further provides a membrane system comprising an enzyme layer surrounding the sensing region of the electrochemically active surface and the at least one nub. As admitted in the Office Action, membranes 18 and 19 of Brown do not contain enzyme. In this regard, the Office Action cites Cozzette for including an enzyme in a membrane. The Office Action states that "it would have been obvious to modify

Brown to locate an enzyme in the membrane, as it is merely the substitution of one known detection scheme for another." Applicants disagree. Membranes 18 and 19 are selectable for their particular permeability to carbon dioxide (membrane 18) or to ions (membrane 19). Thus, it is the permeability of the membrane that is utilized to control the flow through and measurement of the desired element. Brown does not suggest the possibility of providing an enzyme in the membrane to react with an analyte to provide a reaction product that may be detected by an electrode. In fact, including such a component in the membrane would be counter to the express teachings of Brown that require a specifically selected permeable barrier membrane. In Brown, a reaction is not contemplated, nor desired, as the particular desired ion must pass unchanged through the barrier and be detected at the active surface. The sensor in Brown is utilized to detect relatively small ions (CO_2, H, K, and Ca) because a membrane selected to allow larger compounds through the membrane (such as glucose) would not work well in such as system as too many interfering compounds would also be allowed to pass through the permeable membrane. For the above reasons, Applicants submit that an insufficient reason for the combination has been provided in the Office Action.

For all the above-stated reasons, Brown and Cozzette fail to teach at least one feature of claim 1, and therefore, claim 1 is patentable over Brown and Cozzette.

Claims 2-4, 6-8, 24, and 25 depend directly or indirectly on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Brown and Cozette, so are claims 2-4, 6-8, 24, and 25 by virtue of at least their dependency.

103(a) Rejection of Claim 26

Claim 26 is rejected under 35 USC 103(a) as being unpatentable over Zier. Applicants respectfully traverse the rejection in light of the remarks below.

Claim 26 depends on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Zier, so is claim 26 by virtue of at least its dependency. Whether examined under 35 USC 102(b) or 103(a), Zier fails to teach or suggest every element of claim 1 or claim 26. Thus, claim 26 is patentable over Zier.

103(a) Rejection of Claims 8 and 27-28

Claims 8 and 27-28 are rejected under 35 USC 103(a) as being unpatentable over Zier in view of US Patent No. 5,165,407 to Wilson (Wilson). Applicants respectfully traverse the rejection in light of the remarks below.

Claims 8 and 27-28 depend directly or indirectly on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Zier, so are claims 8 and 27-28 by virtue of at least their dependency. Wilson fails to overcome the deficiencies of Zier discussed above. Thus, claims 8 and 27-28 are patentable over Zier and Wilson for at least the reasons discussed above with respect to claim 1.

Conclusion

In view of the foregoing, Applicant respectfully submits that claims 1-4, 6-8, 24-28, and 31-35 are in condition for allowance, and early issuance of the Notice of Allowance is respectfully requested.

If the Examiner has any questions, he is invited to contact the undersigned at (503) 796-2844. Please charge any shortages and credit any overages to Deposit Account No. 500393.

Respectfully submitted,

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